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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,150	08/20/2003	Jean-Marie Stutzmann	USST98048USDIV	6499
5487	7590	07/28/2005	EXAMINER	
			WHITE, EVERETT NMN	
ROSS J. OEHLER AVENTIS PHARMACEUTICALS INC. ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807		ART UNIT		PAPER NUMBER
		1623		
DATE MAILED: 07/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/644,150	STUTZMANN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	EVERETT WHITE	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 June 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2-19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

1. The amendment filed June 1, 2005 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
  - (A) Claim 1 has been canceled;
  - (B) Claims 2 and 7-19 have been amended;
  - (C) Comments regarding Office Action have been provided drawn to:
    - (I) Double patenting rejection, which has been withdrawn;
    - (II) 112 2<sup>nd</sup> paragraph rejection, which has been withdrawn;
    - (III) 102(a) rejection, which has been maintained for the reason of record;
    - (IV) 103 rejections, rendered moot by new ground of rejection.
2. Claims 2-19 are pending in the case.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

4. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 recites how the low molecular weight heparin is obtained. The recitation is not further limiting. It does not matter how the heparin is obtained.
5. No argument was presented regarding the objection of Claim 8.

### ***Claim Rejections - 35 USC § 112***

6. Claims 2, 3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 does not clearly establish what the term "effective amount" is intended to accomplish or does not clearly set forth a specific amount, which renders Claim 2 and Claims 3 and 8, which are dependent from Claim 2, indefinite.

7. Applicant's arguments with respect to Claims 2, 3 and 8 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 2 stands rejected under 35 U.S.C. 102(b) as being anticipated by VonArnim (WO 94/18988) for the reason set forth on page 3 of the Office Action mailed August 11, 2004.

10. Applicant's arguments filed June 1, 2005 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that "multiple sclerosis" is not a motoneuron disease. The Office Action filed August 11, 2004, sets forth in the rejection of the claims over the VonArnim patent that "multiple sclerosis" is within the scope of motoneuron diseases. This classification of multiple sclerosis is further evidence in other references including the "American Speech Language Hearing Association, 1997, pp 1-6", which was mentioned by Applicants in the instant response to the Office Action (see the 1st paragraph on page 1 of the reference). This classification of multiple sclerosis is also noted in Engel's U.S. Patent No. 4,608,356, wherein the sentence bridging columns 1 and 2 sets forth that adult-onset primary lateral sclerosis, adrenomyeloneuropathy and multiple sclerosis each involved upper motor neuron dysfunction. It is noted on page 9 of the instant specification, last paragraph, that primary lateral sclerosis (which is cited in the Engel patent along with multiple sclerosis) is listed as an example of a motoneuron disease. Exhibits A, B, C and D (filed June 1, 2005) which are presented by Applicants, which set forth prior art references to support Applicants argument that multiple sclerosis is different from motoneuron diseases are noted. However, in view of the teachings of the American Speech Language Hearing Association reference, the Engel patent, and the lack of a

clear definition for motoneuron diseases in the instant specification which would clarify the metes and bounds of motoneuron diseases of the instant invention, the rejection of Claim 2 under 35 U.S.C. 102(b) as being anticipated by the VonArnim patent is maintained for the reasons of record.

***Claim Rejections - 35 USC § 103***

11. Claims 2 and 4-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over VonArnim (WO 94/18988) for the reasons disclosed on pages 5 and 6 of the Office Action mailed August 11, 2004.

Applicants claim a method for treating a motoneuron disease in a patient by increasing the survival and/or growth of motoneurons in said patient comprising administering to said patient a pharmaceutically effective amount of a low molecular weight heparin. Additional limitations in the dependent claims include specific types of motoneuron diseases and low molecular weight heparin of specific types and of specific molecular weights.

The VonArnim patent discloses treatment of diseases that include multiple sclerosis (see page 1, 1<sup>st</sup> paragraph) by administering to patients pharmaceuticals that may be selected as low-molecular-weight heparin (see page 5, 3<sup>rd</sup> paragraph). The multiple sclerosis of the VonArnim patent appears to be within the scope of the motoneuron diseases of the instant claims (see above argument under the 35 U.S.C. 102 rejection). The instant claims differ from the VonArnim patent by setting forth low-molecular-weight heparin of specific types and of specific molecular weights. However, all the compounds that are set forth in the instantly claimed method are analogous since they all are classified as low-molecular-weight heparin. One having ordinary skill in the art would have been motivated to employ the method of the prior art with the expectation of obtaining a desired result because the skilled artisan would have expected the analogous compounds to react similarly. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicant invention to replace the low-molecular-weight heparin, which is administered to patients to treat multiple sclerosis in the VonArnim patent with a similarly compound classified as low-molecular-

weight heparin in view of their closely related structures and the resulting expectation of similar therapeutic properties.

12. Applicant's arguments with respect to claims 2 and 4-19 have been considered but are moot in view of the new ground(s) of rejection.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over VonArnim (WO 94/18988) as applied to Claims 2 and 4-19 above, and further in view of Engel's U.S. Patent No. 4,608,356.

Applicants claim a method for treating a motoneuron disease in a patient in Claim 2 and further recite specific motoneuron diseases in Claim 3, which include amyotrophic lateral sclerosis, progressive spinal muscular atrophy, infantile muscular atrophy or lateral sclerosis.

The information disclosed in the above rejection over the VonArnim document is incorporated into the current rejection of Claim 3. The instant claims differ from the VonArnim document by reciting specific motoneuron diseases which are not set forth in the VonArnim document. However, the Engel patent established a nexus between multiple sclerosis and lateral sclerosis (which is specifically recited in instant Claim 3) by setting forth in the sentence bridging columns 1 and 2 that "adult-onset primary lateral sclerosis, adrenomyeloneuropathy and multiple sclerosis each involved upper motor neuron dysfunction". A person of ordinary skill in this art would be motivated to combine the teachings of the VonArnim document with that of the Engel patent since both references discuss treatments of motoneuron diseases. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute treatment of multiple sclerosis in the VonArnim document with a treatment of lateral sclerosis in view of the recognition in the art, as suggested in the Engel patent on column 2, lines 6-10, that it is apparent that any therapeutic agent which would alleviate the motor neuron-related symptoms of one specific motoneuron disease would have broad applicability in the treatment of a wide variety of neurologic functions.

14. Applicant's arguments with respect to Claim 3 have been considered but are moot in view of the new ground(s) of rejection.

***Summary***

15. All the claims are rejected.

***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Examiner's Telephone Number, Fax Number, and Other Information***

17. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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James O. Wilson  
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